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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,876	11/20/2001	Susana Salceda	DEX-0285	3434

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EXAMINER	
SPIEGLER, ALEXANDER H	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,876	SALCEDA ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants' response filed on September 17, 2003. Currently, claims 1-5, 7-9 and 15 are pending. This action is made NON-FINAL.

Specification

2. The disclosure is objected to because of the following informalities:

A) A blank appears at page 75, line 16: "yeast_mating factor".

B) The disclosure (see page 146, for example) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-5, 7-9 and 15 over "under stringent conditions" because it is not clear as to what is meant by "stringent conditions". That is, it is not clear as to what specific conditions are required for "selective hybridization under stringent hybridization conditions". The specification

does not specifically define what conditions are necessary for "stringent conditions". Applicants should amend the claims to specify the specific conditions (e.g., xSSC, temperature, etc.).

Applicants Arguments

Applicants argue the specification on page 14, line 21 through page 16, line 14 provides a clear and definite teaching to what is meant by "selectively hybridizing" under stringent conditions. (see page 2 of Applicants' remarks)

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, as Applicants have indicated, from page 14, line 21 through page 16, line 14 discusses general hybridization conditions. However, these pages discuss a various range of possible conditions, which can be considered as "stringent conditions" (e.g., 6X SSC at 68^0C, 6X SSC at 55^0C, 6X SSC at 42^0C, the temperature can be changed from 68^0C to 42^0C, as well as the alteration of washing conditions, e.g., 0.1x SSC, 1x SSC, 4x SSC, see pages 15, line 24 to page 16, line 13). Given this range of possible conditions that may be considered to be "stringent", the skilled artisan is not given a clear and definite teaching of what is meant by "stringent conditions". Accordingly, because of the lack of clarity as to what is meant by "stringent conditions", absent specific conditions in the claims, the rejection is maintained.

B) Claims 1-5, 7-9 and 15 are indefinite over Claim 1, step (d), because it is not clear as to how "a nucleic acid molecule having at least *80% sequence identity* to the nucleic acid molecule of (a) or (b)" and encodes "a prostate specific protein comprising SEQ ID NO: 135". (emphasis added) First, it is not clear as to how a nucleic acid molecule that has an 80% sequence identity to a SEQ ID NO: 27 or a nucleic acid that molecule that encodes SEQ ID NO:

135, can also encode SEQ ID NO: 135. That is, if the nucleic acid molecule of (d) has *only* an 80% sequence identity to a sequence that encodes SEQ ID NO: 135, it is not clear the nucleic acid of (d) can also encode SEQ ID NO: 135. The specification does not provide any teachings as to what nucleic acids can be mutated and still encode SEQ ID NO: 135. Furthermore, it is not clear as to whether (d) refers to the nucleic acid of (a) or (b), because (b) can be interpreted as being a nucleic acid comprising "a" nucleic acid sequence of SEQ ID NO: 27. Thus, if it not clear as how the nucleic acid molecule of (d) can have an 80% sequence identity to "a" nucleic acid.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-5, 7-9 and 15 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial or credible asserted utility, or a well established utility.

The pending claims have been reviewed in light of the Utility Examination Guidelines in the Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001, as well as the MPEP and existing law.

I. *The specification does not assert a specific utility because the Applicant has not disclosed a specific biological activity of the claimed invention and has not reasonably correlated that activity to a disease condition.*

MPEP 2107.01 states:

> A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful....A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. ***Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention.***

In the instant case, the specification is silent as to any teachings, results or correlations between the claimed nucleic acid (SEQ ID NO: 27) and prostate cancer. For example, none of the tables or examples on pages 116-141 shows a nexus between the claimed nucleic acid and prostate cancer. Accordingly, because no specific biological activity of SEQ ID NO: 27 (or the polypeptide encoded, SEQ ID NO: 135) has been disclosed, nor has any activity of the claimed nucleic acids (or the polypeptides encoded by them) been reasonably correlated with a disease condition, the specification does not support a specific utility for the claimed invention.

II. *The specification does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use.*

MPEP § 2107.01 states:

> A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

In order for a nucleic acid to be useful for detection, diagnosis and/or treatment of a disease, there must be a well established or disclosed correlation or relationship between the claimed nucleic acid and a disease or disorder. The presence of a nucleic acid in tissue that is

derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed nucleic acid to be used in a diagnostic manner. Many nucleic acids are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed nucleic acid is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed nucleic acid as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner v. Manson*, 148 USPQ 696 (US SupCt 1966).

In the instant case, the specification does not teach any relationship between the claimed nucleic acid and prostate cancer. At best, Applicants have proposed a starting point for further research in order to determine whether SEQ ID NO: 27 is correlated with prostate cancer. Accordingly, the disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

III. *The specification is not supported by credible utility because the asserted utility is not believable to one of ordinary skill in the art based on the totality of evidence and reasoning provided.*

In the instant case, the specification does not disclose a connection between the presence or expression of SEQ ID NO: 27 (or the other claimed nucleic acids) and prostate cancer. Absent any evidence linking the claimed nucleic acids and prostate cancer, it is not credible that the claimed nucleic acids are diagnostic of prostate cancer.

IV. *The specification is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics on the invention.*

MPEP 2107 states:

"An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible."

Applicants have provided little to no evidence of the characteristics of the specifically claimed nucleic acid, the specification is not specific, substantial or credible, and based on Applicants assertion that the claimed nucleic acid is new, it is not apparent as to how "a person of ordinary skill in the art would immediately appreciate why the invention is useful". This is evidenced by the fact that further research would need to be carried out by the skilled artisan even given Applicants' claimed nucleic acid. For these reasons, the specification is not supported by a well-established utility.

Accordingly, the claimed invention lacks a specific, substantial or credible utility, or in the alternative, a well-established utility.

Applicants Arguments

Applicants argue the "specification provides a correlative or casual relationship between expression of the claimed nucleic acid molecule and the disease", and therefore, the specification

provides a specific and substantial utility for the claimed invention. (see page 4 of Applicants remarks) Applicants also rely on *Nelson v. Bowler* for the assertion that SEQ ID NO: 27 constitutes a pharmacological activity relevant to the asserted use as a diagnostic for cancer. (see page 4 of Applicants remarks)

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons. First, the specification provides no data or evidence that the claimed nucleic acids are overexpressed in disease samples as compared to normal samples. For example, while the specification teaches an example of expression analysis, wherein Sqpro045 (SEQ ID NO: 77) appears to be overexpressed in prostate cancer samples, as compared to normal samples; and additionally, SEQ ID NO: 77 appears to be overexpressed in prostate tissue compared to other tissues of prostate cancer samples (pgs. 121-123), the specification is silent as to any expression data of SEQ ID NO: 27 or the other claimed nucleic acids. Second, Applicants reliance on *Nelson v. Bowler* , 206 USPQ 881 (CCPA 1980) is not persuasive, and the instant case can be distinguished from that in *Nelson*. In *Nelson*, BP and GC-SMS tests were carried out, wherein the court concluded that "a correlation between test results and pharmacological activities has been established" *Id.* at 883, 885. In the instant case, no tests have been carried out using SEQ ID NO: 27, and no pharmacological activities have been established. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 112

7. Claims 1-5, 7-9 and 15 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, in addition to the reasons above, the specification is further not enabling for the following reasons.

MPEP 2164.01 states:

> Even though the statute does not use the term 'undue experimentation,' it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The *Wands* court outlined several factors to be considered in determining whether a disclosure would require undue experimentation. These factors include, but are not limited to:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) ***Nature of the Invention & Breadth of the Claims***

The claims are drawn to isolated nucleic acid molecules comprising a nucleic acid sequence encoding SEQ ID NO: 135, "a" nucleic acid of SEQ ID NO: 27, nucleic acid molecules that "selectively hybridize under stringent conditions" to a nucleic acid that encodes SEQ ID

NO: 135 or "a" nucleic acid of SEQ ID NO: 27, and nucleic acids having at least 80% sequence identity to a nucleic acid sequence encoding SEQ ID NO: 135 or "a" nucleic acid of SEQ ID NO: 27.

Thus, the claims are drawn to a large genus of possible nucleic acids, including sequences from other species, mutated sequences, and allelic variants having different functional activities than that of the nucleic acid (SEQ ID NO: 27) encoding the polypeptide of SEQ ID NO: 135.

(2) ***Relative Skill of those in the Art, State of the Prior Art, Amount of Direction or Guidance Presented & Presence or Absence of Working Examples***

The specification teaches SEQ ID NO: 27 was identified by mRNA subtraction analysis (see page 116). However, **the specification does not teach or provide**:

1) the predicted chromosomal location of this sequence (pages 118-9);

2) any post-transnational modifications of the polypeptide encoded by SEQ ID NO: 27 (pages 126-7);

3) any guidance as to modifications of nucleic acids that have at least 80% sequence similarity and encode SEQ ID NO: 135;

4) any guidance as to how to make or alter nucleic acid sequences, or any variants falling within the claimed nucleic acid molecules, and still have the function of SEQ ID NO: 27.

5) any critical domains, if any, of the polypeptide encoded by the claimed nucleic acid molecules; or

6) any examples, assays or expression data using SEQ ID NO: 27 (see pages 116-141).

Accordingly, the specification is silent as to any examples of expression data of SEQ ID NO: 27, any assays using SEQ ID NO: 27, or any guidance relating to the use SEQ ID NO: 27, other than its nucleic acid sequence and that it encodes SEQ ID NO: 135.

The prior art is silent as to any teaching of SEQ ID NO: 27, and therefore, the relative skill in the art in determining a use for SEQ ID NO: 27 is high.

(3) ***Quantity of Experimentation Necessary & the Unpredictability of the Art***

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art.

In the instant case, the specification, nor the prior art teach the association/and or correlation for SEQ ID NO: 27, and therefore, the skilled artisan would not know how to use the claimed nucleic acids. Any potential results that the skilled artisan would arrive at would be unpredictable given the lack of guidance in the specification and the prior art. Additionally, given the lack of guidance in the specification or the prior art, as to how to alter the claimed nucleotide molecules and retain the activity of SEQ ID NO: 27, the making and using of the nucleic acid molecules encompassed by the claimed invention would also be unpredictable.

In order to carry out making and using of the claimed nucleic acids, the experimentation required by the skilled artisan would be considered undue. First, the skilled artisan would have

to experiment by altering any of the plurality of possible sequences encompassed by the claims to determine what sequences can be altered, and how they can be altered, and still retain the function of SEQ ID NO: 27. Additionally, once the sequences were obtained, the skilled artisan would have to carrying out expression analysis studies on many samples from different tissues from both normal and diseased test subjects. Following this experimentation, the skilled artisan would have to determine whether the sequences are specific for a disease state. Such experimentation requires a large amount of trial and error analysis, with little to no starting point, absent any teaching in the specification (see above), wherein the results of such analysis are unpredictable, and is therefore considered undue.

In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. However, "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Written Description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-5, 7-9 and 15 are directed to nucleic acids comprising a nucleic acid sequence encoding SEQ ID NO: 135, "a" nucleic acid of SEQ ID NO: 27, nucleic acid molecules that "selectively hybridize under stringent conditions" to a nucleic acid that encodes SEQ ID NO: 135 or "a" nucleic acid of SEQ ID NO: 27, and nucleic acids having at least 80% sequence identity to a nucleic acid sequence encoding SEQ ID NO: 135 or "a" nucleic acid of SEQ ID NO: 27.

Applicants disclose SEQ ID NO: 27.

Claims reciting "comprising", "a" nucleic acid of SEQ ID NO: 27, "at least 80% sequence identity" or nucleic acids that "selectively hybridize under stringent conditions" to a nucleic acid that encodes SEQ ID NO: 135 or "a" nucleic acid of SEQ ID NO: 27, are inclusive of sequences from other species, mutated sequences, allelic variants, full-length genes, genomic DNA, for example, all which have different functions than that of the nucleic acid in SEQ ID NO: 27. Thus, the claims broadly encompass many types of nucleic acids (e.g., allelic variants, mutated sequences, genomic DNA, etc.), whereas, the specification only teaches SEQ ID NO: 27.

The specification does not reasonably convey to one skilled in the art that Applicants were in possession of the claimed invention, because the specification does not describe the specific structures (e.g., promoters, enhancers, 5' or 3' untranslated regions), which are found in genomic DNA (i.e., the instant claims), or any of the other types of nucleic acid molecules

encompassed by the broadly claimed invention. More specifically, the specification only describes SEQ ID NO: 27, which encodes SEQ ID NO: 135, but does not describe the other types of nucleic acid molecules encompassed by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117)." (emphasis added)

In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only one member of the broadly claimed genus has been defined by structure, i.e., SEQ ID NO: 27. No genomic sequences flanking SEQ ID NO: 27, nucleic acids sequences having at least 80% sequence identity to SEQ ID NO: 27 (which encode SEQ ID NO: 135), nucleic acid molecules that "selectively hybridize under stringent conditions" to a nucleic acid

that encodes SEQ ID NO: 135 or "a" nucleic acid of SEQ ID NO: 27 have been defined by structure. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., location of intron/exon boundaries, length of introns, length of 5' or 3' untranslated regions, which nucleic acids can be altered to have at least 80% sequence identity to SEQ ID NO: 27 and encode SEQ ID NO: 135, etc.). In the instant case, no such identifying characteristics have been provided for any of the polynucleotides. While at the time of filing, Applicants were in possession of SEQ ID NO: 27, Applicants were not in possession of the broadly claimed genus.

Applicant's attention is also drawn to the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph, Written Description Requirement" (published in Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

Accordingly, because the specification does make clear that Applicants were in possession of the claimed invention at the time the application was filed, and because the claims are broadly drawn to encompass other nucleic acid molecules not taught or described in the specification, the claims lack adequate written description.

Applicants Arguments

Applicants argue the claims have been amended to recite functional language, as well as, the inclusion of "under stringent conditions", thus allegedly providing adequate written description. Additionally, Applicants' state, "multiple ESTs support SEQ ID NO: 27 being approximately the full length gene." (see page 7 of Applicants remarks)

Response to Applicants Arguments

Applicants arguments have been considered, but are not persuasive for the following reasons. First, Applicants have not described a representative number of species (of the claimed genus) by their complete structure. Only one member of the broadly claimed genus has been defined by structure, i.e., SEQ ID NO: 27. In addition, Applicants have not described any other sufficient, relevant identifying characteristics (e.g., see above) of the claimed genus. Applicants have amended the claims to recite functional language, but the specification does not describe which nucleic acids can be altered to have at least 80% sequence identity to SEQ ID NO: 27 and encode SEQ ID NO: 135. Functional language alone, absent teachings of specific structures (or relevant identifying characteristics) encompassed by the claim language, is not sufficient to provide adequate written description for the claimed genus. Applicants assertion that "multiple ESTs support SEQ ID NO: 27 being *approximately* the full-length gene," does not provide support for the broadly claimed invention. It is not clear as to what sequence length is considered to be "approximately" the full-length gene, how this is determined, or how this demonstrates that Applicants' in possession of the claimed invention. Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraser et al. (WO 99/57280).

Fraser teaches a nucleic acid molecule comprising "a" nucleic acid of SEQ ID NO: 27, nucleic acid molecules that "selectively hybridize under stringent conditions" to "a" nucleic acid of SEQ ID NO: 27, and nucleic acids having at least 80% sequence identity to "a" nucleic acid of SEQ ID NO: 27 (see N_Geneseq Accession No. AAZ55077). It is noted that the claims encompass nucleic acids comprising "a" nucleic acid, and therefore, the 18mer taught by Fraser is considered to anticipate the claimed invention. In other words, because the claims recite "a" nucleic acid, the claims include portions of SEQ ID NO: 27, wherein the portions may be of any length. Furthermore, because the claims recite, "comprising", the claims include nucleic acids which contain this portion and an unlimited number of flanking nucleotides. With respect to claim 15, Fraser teaches a kit comprising a means for determining the presence of the nucleic acid molecule of claim 1 in a sample of a patient (see page 48).

Due to the voluminous nature of WO 99/57280 (totaling 1453 pages), only the relevant pages of the document have been included herein (pages 1-51 and 153).

12. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al. (USPN 4,800,159).

Mullis et al. teach a kit comprising a means for determining the presence of the nucleic acid molecule of claim 1 in a sample of a patient (e.g., agent for polymerization, nucleoside triphosphates, means for detecting hybrids of a probe and a sequence, etc.) (see col. 3, for example).

Conclusion

13. No claims are allowable.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199 or at (571) 272-0747 after January 13, 2004. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
December 3, 2003

CARLA J. MYERS
PRIMARY EXAMINER